

SEP 4 - 2007

REMARKS/ ARGUMENTS

Objections to the Claims

Applicant has amended Claim 19 to address the substance of the Examiner's objection and to comply with Applicant's specification. The claim amendments now make the objection to independent Claim 19 and dependent Claims 20-25 moot and therefore Applicant respectfully requests that the Examiner withdraw the objection and allow Claims 19-25.

Rejection under 35 U.S.C. 112, second paragraph

Applicant has amended Claim 19 to address the substance of the Examiner's rejection and to address the subject of Applicant's claimed invention by further explaining how the buccal test is different. This particular test includes a dip-tube that allows for the removal of small undissolved particles. The removal simulates the swallowing aspect of the buccal cavity which is distinguished from the mechanics of the GI system which does not comprise a swallowing element. Applicant feels that the claim amendments now make the rejection of independent Claim 19 and dependent Claims 20-25 moot and therefore respectfully request that the Examiner withdraw the rejection and allow Claims 19-25.

Rejection under 35 U.S.C. 103(a)

The Examiner has rejected Claims 19-25 as being unpatentable over Compton US 4,594,902 et al in view of Olson US 3,620,625. The combination of Compton in view of Olsen does not lead one to Applicant's claimed invention because there is no teaching of the removal undissolved solids in a buccal dissolution test.

The sampling apparatus of Compton is not a disclosure of the buccal dissolution test process of the present invention. Compton discloses no more than a robotic arm for

retrieving samples. Compton withdraws samples and in some cases passes them in a filter.

Conversely, while Olsen does disclose a dissolution test process, Olsen discloses a dissolution test for systems where complete dissolution is favorable, such as gastrointestinal tests. One such difference between buccal dissolution tests and other types of tests lies in the removal of undissolved portions of test sample. Neither Compton nor Olsen teaches the removal of undissolved portions of test sample. In fact, in Olsen, complete dissolution is favored making it preferred to leave the undissolved portions in the test sample. *Olson, col.2, lns. 24-28*. One would not look to Olson for an in vitro buccal dissolution test, where incomplete dissolution is favored, because Olson is concerned with measuring the dissolution rate of a medicament over time not for dissolution of a test sample within a few moments. *Id.* Olson is continuously passing a dissolution fluid across a test sample in order to achieve the sample's concentration gradient. One might argue that Olson teaches away from Applicant's invention because complete dissolution is necessary to measure the concentration gradient. As aforementioned, in Applicant's invention, complete dissolution is not favored. *Present application page 1, lines 17-25*. The test samples are left in the cell on the order of a few seconds to a few minutes. Undissolved portions are removed by the dip-tube. Removal of undissolved solids by Applicant's claimed feature is contrary to the teachings of Olson.

Olson discloses in the abstract "an apparatus for the measurement of dissolution rates of solid materials such as tablets, capsules, modules or the like." In fact, even the illustration shows a whole pill sitting inside of a dissolution chamber. A solid pill would have been removed from Applicant's system by way of Applicant's claimed dip-tube element.

Even if one were to combine the teachings of Compton in view of Olsen, one would not end up with Applicant's claimed invention. At best one would end up with a testing apparatus useful for dissolution systems where complete dissolution is favored such as

measuring dissolution in the gastro-intestinal system. There is no teaching in the combination of references of the removal of undissolved solids, by a dip-tube structure, for the testing of incomplete dissolution.

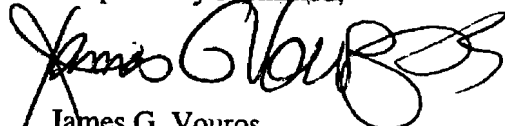
Thus, in light of Applicant's claim amendment and argument, the rejection of independent Claim 19 and dependent Claims 20-25 is now moot and Applicant respectfully requests that the Examiner withdraw the rejection and allow Claims 19-25.

CONCLUSION

Applicant has provided a complete listing of the claims and remarks for the Examiner's review. The pending claims, Claims 19-25, are in condition for allowance and Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Applicant hereby authorizes the Commissioner to charge any fees which may be required or credit for overpayment for entry of this Amendment to Deposit Account No. 18-1850.

Respectfully submitted,



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September 4, 2007